Silmax implants

NOV 21 2000

K002633

Enclosure I

510(k) Summary

Trade Name
Silmax Pectoral Implant

Common Name
Silicone Elastomer Pectoral Implant

Substantial Equivalence
The Silmax Pectoral Implant designs are substantially equivalent in material and function, performance and safety to the Hanson Pectoral Implant, Manufactured and Marketed by Hanson Medical, Inc. 510(k) K973729; & Seare Biomedical K982762.

Material Safety
The silicone materials used to make Silmax Pectoral Implants are routinely tested for Appearance, Durometer, and Cytotoxicity. MSDS information is available from the manufacturer. Materials used in Silmax Pectoral Implants are FDA master-filed materials from Nusil Technologies, Inc's, healthcare, implantable-grade, silicones (MAF-612.)

Device Description
Available as a right and left (mirror design), the Silmax Pectoral Implant is a large concave/convex, oval-shaped silicone elastomer implant designed to be implanted in the pectoral region of the body. There will be 3 Styles in all, with 2 (two) possible orientations, available in 5 sizes. Sizes will range from the smallest size: 9 (nine) centimeters high, by 14 (fourteen) centimeters long, with 1.5cm of projection to the largest size: 13.5cm x 16.3cm x 2.5cm, respectively. The implant is designed to be inserted in the submuscular space provided by the surgeon during the surgery by means of a "pocket dissection" and insertion into the submuscular pectoralis region. Surface characteristics will vary from smooth to degrees of texturing as desired by the surgeon and requirements of each patient.

Indications for use
Silmax Pectoral Implants are indicated for use in patients who require aesthetic, corrective or reconstructive surgery. The appropriate size of the implant will be determined prior to surgery by an examination of the patient requiring the surgery. Measurements of pre-existing tissue should be noted so that there will be adequate tissue covering the implant.

Contraindications
Silmax Pectoral Implants are contraindicated for use if there are any of the following: Insufficient tissue covering or unusual skin or muscle atrophy. Any pre-existing patient drug use, conditions or diseases, which put the patient at higher, risk during implant surgery. Any condition or diseases that compromises the surgeon's ability to create a large enough pocket to insert the implant and avoid explant surgery.

Clinical Tests: None
Longitudinal Tests: None
Adverse Safety and Efficacy Tests: None

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2000

Mr. Rob Fritzenkotter
Silmax Implants
P.O. Box 8141
La Jolla, California 92038

Re: K002633
Trade Name: Silmax Pectoral Implant
Regulatory Class: Unclassified
Product Code: MIC
Dated: August 18, 2000
Received: August 23, 2000

Dear Mr. Fritzenkotter:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K002633 Page ____ of ____

510(k) NUMBER (IF KNOWN): K002633

DEVICE NAME: SILMAX PECTORAL IMPLANT

INDICATIONS FOR USE:

Indications for use:

Silmax Pectoral Implants are indicated for use in patients who require aesthetic, corrective or reconstructive surgery affecting their pectoralis muscle structures. The appropriate size of the implant will be determined prior to surgery by an examination of the patient requiring the surgery. Measurements of pre-existing tissue should be noted so that there will be adequate tissue covering the implant.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter-Use ___ (Optional Format 1-2

for Mark N. Melkerson

(Division Sign-Off)
Division of General Devices
510(k) Number K002633